



IFW
BAC

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

John G. Babish, et al.

Application No.: 09/919,506

Filed: 31 July 2001

For: COMBINATIONS OF SESQUITERPENE
LACTONES AND DITERPENE LACTONES :
OR TRITERPENES FOR SYNERGISTIC :
INHIBITION OF CYCLOGENASE-2 :

Group Art Unit: 1654

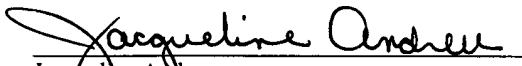
Examiner: Patricia A. Leith

Confirmation No.: 2768

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted (571-273-8300) to the USPTO, on the date indicated below.

Date: August 31, 2006


Jacqueline Andrea

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER


Applicant encloses herewith for filing in connection with the above-referenced patent application the following documents:

- 1) Petition Under 37 C.F.R. §1.181 To Withdraw Holding of Abandonment
- 2) Return Receipt Postcard

The Commissioner is hereby authorized to charge to our Deposit Account No. 50-1133 for any fees required for the prosecution of the subject application.

Respectfully submitted,

Date: 31 August 2006


G. Matthew McCloskey, Reg. No. 47,025
McDermott Will & Emery LLP
28 State Street
Boston, Massachusetts 02109-1775
Telephone: (617) 535-4082
Facsimile: (617) 535-3800



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

John G. Babish, et al.

Application No.: 09/919,506

Filed: 31 July 2001

For: COMBINATIONS OF SESQUITERPENE
LACTONES AND DITERPENE LACTONES
OR TRITERPENES FOR SYNERGISTIC
INHIBITION OF CYCLOGENASE-2

Group Art Unit: 1654

Examiner: Patricia A. Leith

Confirmation No.: 2768

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted (571-273-8300) to the USPTO, on the date indicated below

Date: 8/31/06

Jacqueline Andrea

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. §1.181 TO WITHDRAW
HOLDING OF ABANDONMENT

Concerning the above-referenced application, Applicant respectfully petitions for the Office to withdraw the holding of abandonment based on failure to submit a proper reply to the Office Action of 30 November 2004 under 37 C.F.R. § 1.113(a).

As explained in the following statements, Applicant timely responded to the Office Action of 30 November 2004 by filing (i) a Notice of Appeal on 31 May 2005 (30 May 2005 being a holiday), and (ii) a Request for Examination with Petition for Extension of Time and an Amendment, all on 28 December 2005. *Consequently the application should not be considered abandoned. Further, as the Amendment filed placed the application in condition for allowance, a Notice of Allowance is requested for the subject application.*

For the subject application, the Office mailed a final Action on 30 November 2004 as prepared by Examiner Leith. In the Action, claims 1-15, 43-57, 63, and 64 were rejected and dependent claims 16-20 and 58-62 were objected to for depending on a rejected claim. Claims 16-20 and 58-62 were, however, indicated as being allowable if written in independent form.

Applicant notes that claims 16-20 and 58-62 of the application had previously been amended in independent form by way of the Amendment filed on 02 September 2004. The Office's PAIR database confirms that claims 16 and 58 of the subject application were amended in independent form by the Amendment filed 02 September 2004.

On 02 March 2005, Applicant's attorney Simona A. Levi-Minzi discussed the prosecution of the subject application with SPE Campell (who was assigned to the subject application while Examiner Leith was on a leave of absence from the Office). Upon review of the record, Examiner Campell agreed that the allowable claims 16-20 and 58-62 should be allowed, suggesting that an After-Final response be filed, canceling the rejected claims in the application as well as asking for allowance of claims 16-20 and 58-62. A copy of the corresponding memorandum to Applicant's attorney's file prepared by Attorney S. Levi-Minzi on 02 March 2005 is attached hereto as **Exhibit A**.

In response to the referenced Office Action, Applicant's present attorneys timely filed: (i) a Notice of Appeal From the Examiner to the Board of Patent Appeals and Interferences, (ii) a Petition for Extension of Time (three-months) with appropriate fee, and (iii) a Transmittal Letter; all of which items included a signed and dated certificate of mailing in accordance with 37 C.F.R. § 1.8 on 31 May 2005. These items were timely filed as the Office was closed on 30 May 2005 for Memorial Day. A copy of these submitted documents are attached hereto as **Exhibit B**. The Office received the Notice of Appeal and related papers on 02 June 2005, as reflected in the prosecution history of the subject application, available on the Office's PAIR database.

On 28 December 2005, Applicant's present attorneys timely filed (i) a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 with appropriate fee, (ii) a Petition for Extension of Time (five-months) with appropriate fee, (iii) an Amendment fully responsive to the Office Action of

30 November 2004, and (iv) a Transmittal Letter; all of which items included a signed and dated Certificate of Mailing in accordance with 37 C.F.R. § 1.8, indicating a mailing date of 28 December 2005. An Acknowledgement Postcard was filed for the submission of items (i-iv). Each item (i-iv) was listed on the Acknowledgement Postcard, which was returned from the Office with a date stamp indicating receipt by OIPE on 03 January 2006. The referenced RCE and associated items with date-stamped Acknowledgement Postcard are attached hereto as *Exhibit C*. Applicant notes that the filing date of items (i-iv) was within the period to file an appeal brief under 37 C.F.R. § 1.192(a) as extendable under 37 C.F.R. § 1.136(a).

The Amendment filed with the RCE canceled claims 1-15, 43-57, 63, and 64, thus placing the application in condition for allowance. The Amendment further indicated that claims 16-20 and 58-62 had previously been amended in independent form by way of the Amendment filed for the application on 02 September 2004.

On 27 March 2006, the Office mailed a Notice of Abandonment for the subject application to Applicant's previous attorneys. The Notice of Abandonment indicated that the application was abandoned because the proposed reply received on 02 June 2005 did not constitute a proper reply under 37 C.F.R. § 1.113(a). Applicant's present attorneys received the Notice of Abandonment on 28 April 2006 from Applicant's previous attorneys.

On 22 August 2006, Applicant's present attorney, G. Matthew McCloskey, placed a call to Examiner Leith regarding the application to inquire about the Notice of Abandonment. Examiner Leith was unavailable at the time of the call, however, Examiner Leith later responded by voice message, informing that she would be on leave and unavailable subsequent to 25 August 2006. On 24 August 2006 attorney McCloskey again called Examiner Leith, who again was unavailable, and left a voice message, learning that SPE Terry McKelvey should be contacted for matters previously handled by Examiner Leith.

On 29 August 2006, attorney McCloskey placed a call to SPE McKelvey and discussed the subject application. SPE McKelvey was unaware of the RCE and Amendment filed on 28 December

Serial No. 09/919,506
Petition Under 37 CFR § 1.181 to Withdraw Holding of Abandonment
Reply to Notice of Abandonment
Date: 31 August 2006

2005, noting that the RCE and Amendment were not indicated in the PAIR database. Upon learning of the submission of the referenced RCE, Amendment, and the corresponding Acknowledgement Postcard as stamped by OIPE, SPE McKelvey provided that the Amendment and RCE, if complete under 37 C.F.R. § 1.114, would have *constituted a proper response* to the final Office Action of 30 November 2004. Applicant submits that the RCE as filed was complete under 37 C.F.R. § 1.114.


For the foregoing reasons, Applicant respectfully petitions for the Office to withdraw the holding of abandonment for the subject application and, further, to resume examination based on the Amendment filed 28 December 2005. Moreover, as the Amendment filed on 28 December 2005 placed the application in condition for allowance, a Notice of Allowance is requested for the application.

No fee is believed due for the submission of this petition, however, the Commissioner is hereby authorized to charge any fees that are required for the subject application, or credit any overpayment, to Deposit Account No. 50-1133.

Respectfully submitted,

McDERMOTT, WILL & EMERY LLP

Date: 8/31/06



Simona Levi-Minzi, Ph.D., Reg. No. 43,750
G. Matthew McCloskey, Reg. No. 47,025
28 State Street
Boston, Massachusetts 02109
Telephone: (617) 535-4049
Facsimile: (617) 535-3800

MEMORANDUM

Date: March 2, 2005

To: 068911.0018
U.S.S.N. 09/919,506

From: Simona A. Levi-Minzi

Re: Telephonic Interview with Examiner Campell

On even date, we had the opportunity to discuss this case with Examiner Campell (the supervisory examiner taking over while the examiner assigned in the case is on maternity leave). Upon a review of the record, Examiner Campell agreed that the allowable claims should be allowed and suggested that we file an after final response canceling the other claims seeking the filing of a divisional and asking for the allowance of the amended claims making reference to the prior amendment.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John G. Babish, *et al.*

Serial No.: 09/919,506

Filed: July 31, 2001

Title: COMBINATIONS OF SESQUITERPENE
LACTONES AND DITERPENE LACTONES
OR TRITERPENES FOR SYNERGISTIC
INHIBITION OF CYCLOOXYGENASE-2

Attorney Docket No.: 068911.0018

Examiner: Patricia A. Leith

Art Unit: 1654

CERTIFICATE OF MAILING (37 C.F.R. § 1.8)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: 5/31/05


Angelo J. Mignanelli

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Enclosed herewith for filing in connection with the above-identified patent application are the following:

- 1) Notice of Appeal From the Examiner to the Board of Patent Appeals and Interferences;
- 2) Petition for a Three-Month Extension of Time; and
- 4) Acknowledgment Postcard.

John G. Babish, *et al.*
U.S.S.N. 09/919,506
Notice of Appeal
Page 2 of 2

This Notice of Appeal is being timely filed on May 31, 2005 since the final due date of May 30, 2005 fell on a Sunday.

Respectfully submitted,



Simona A. Levi-Minzi, Ph.D.
Registration No. 43,750
Attorney for Applicants

McDermott, Will & Emery LLP
201 South Biscayne Blvd.
Suite 2200
Miami, FL 33131
Telephone: 305.347.6528
Facsimile: 305.347.6500

Date: May 31, 2005

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John G. Babish, *et al.*

Serial No.: 09/919,506

Filed: July 31, 2001

Title: COMBINATIONS OF SESQUITERPENE
LACTONES AND DITERPENE LACTONES
OR TRITERPENES FOR SYNERGISTIC
INHIBITION OF CYCLOOXYGENASE-2

Attorney Docket No.: 068911.0018

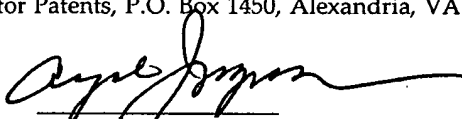
Examiner: Patricia A. Leith

Art Unit: 1654

CERTIFICATE OF MAILING (37 C.F.R. § 1.8)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: 5/21/05


Angelo J. Mignanelli

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT
APPEALS AND INTERFERENCES**

Applicant hereby appeals to the Board of Appeals from the decision dated November 30, 2004.

1. ☒ Appeal fee (37 C.F.R. § 41.20(b)(1))

☒ Small Entity \$250.00
☒ Small Entity status of this application has been
established under 37 C.F.R. § 1.27
2. ☒ Please charge the required fee of \$250.00 pursuant to
3. 37 C.F.R. § 41.20(b)(1)) to Deposit Account No. 50-1133.
4. ☒ The Commissioner is authorized to charge any additional fees or credit
any overpayments to Deposit Account No. 50-1133.

This Notice of Appeal is being timely filed on May 31, 2005 since the final due date of May 30, 2005 fell on a Sunday.

Respectfully submitted,



Simona A. Levi-Minzi, Ph.D.
Registration No. 43,750
Attorney for Applicants

McDermott, Will & Emery LLP
201 South Biscayne Blvd.
Suite 2200
Miami, FL 33131
Telephone: 305.347.6528
Facsimile: 305.347.6500

Date: May 31, 2005

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John G. Babish, *et al.*

Serial No.: 09/919,506

Filed: July 31, 2001

Title: COMBINATIONS OF SESQUITERPENE
LACTONES AND DITERPENE LACTONES
OR TRITERPENES FOR SYNERGISTIC
INHIBITION OF CYCLOOXYGENASE-2

Attorney Docket No.: 068911.0018

Examiner: Patricia A. Leith

Art Unit: 1654

CERTIFICATE OF MAILING (37 C.F.R. § 1.8)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: 5/31/05


Angelo J. Mignanelli

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME

Applicants hereby Petition for a Three (3) Month Extension of Time, up to and including May 31, 2005. Pursuant to 37 C.F.R. § 1.136(a)(3), please charge Deposit Account No. 50-1133 the required fee of \$510.00.

The fee charged reflects the applicants' claims to small entity status pursuant to 37 C.F.R. § 1.27.

The Commissioner is hereby authorized to charge payment of any additional fees associated with the filing submitted herewith or credit any overpayment to Deposit Account No. 50-1133.

This Notice of Appeal is being timely filed on May 31, 2005 since the final due date of May 30, 2005 fell on a Sunday.

Respectfully submitted,



Simona A. Levi-Minzi, Ph.D.
Registration No. 43,750
Attorney for Applicants

McDermott, Will & Emery LLP
201 South Biscayne Blvd.
Suite 2200
Miami, FL 33131
Telephone: 305.347.6528
Facsimile: 305.347.6500

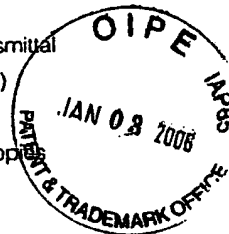
Date: May 31, 2005

Re Application of: **John G. Babish, et al.** Due Date: **December 28,**
Mailed: **December 28, 20**
Mailer: **A. Mignanelli**

For: **COMBINATIONS OF SESQUITERPENE LACTONES AND DITERPENE LACTON
OR TRITERPENES FOR SYNERGISTIC INHIBITION OF CYCLOOXYGENASE-2**
Serial No. **09/919,506** Patent No. Docket: **068911.0012**

In the above matter, the following has been received in the U.S. Patent and Trademark Office on the date stamped hereon.

- | | |
|--|---|
| <input type="checkbox"/> Specification, Abstract and
() Claims — () Total Pages | <input checked="" type="checkbox"/> Extension of time <u>Five Month</u> |
| <input type="checkbox"/> Declaration and Power | <input checked="" type="checkbox"/> Amendment |
| <input type="checkbox"/> Drawing (sheets) | <input checked="" type="checkbox"/> Cert. of Mailing |
| <input type="checkbox"/> Assignment | <input type="checkbox"/> Maintenance Fee Transmittal |
| <input type="checkbox"/> Check \$ | <input type="checkbox"/> Affidavit (w/wo Exhibits) |
| <input type="checkbox"/> Request for Recordation | <input type="checkbox"/> Notice of Appeal |
| <input type="checkbox"/> Information Disclosure Statement | <input type="checkbox"/> Brief () copies |
| <input type="checkbox"/> Small entity verification | <input type="checkbox"/> Issue fee transmittal |
| <input checked="" type="checkbox"/> Request for Continued Examination (RCE) | <input checked="" type="checkbox"/> Transmittal letter |
| <input type="checkbox"/> | |



RECEIVED

JAN 11 2006

MW&E

Simona A. Levi-Minzi

**McDermott
Will & Emery**

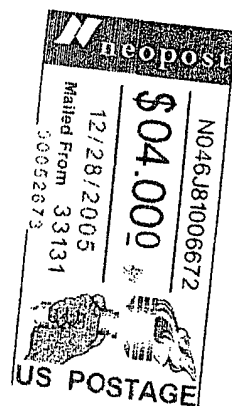
McDermott Will & Emery LLP
201 South Biscayne Boulevard, 22nd Floor
Miami, Florida 33131-4336

MAIL STOP RCE

COMMISSIONER FOR PATENTS

P.O. BOX 1450

ALEXANDRIA, VA 22313-1450



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John G. Babish, *et al.*

Serial No.: 09/919,506

Filed: July 31, 2001

Title: COMBINATIONS OF SESQUITERPENE
LACTONES AND DITERPENE LACTONES
OR TRITERPENES FOR SYNERGISTIC
INHIBITION OF CYCLOOXYGENASE-2

Attorney Docket No.: 068911.0018

Examiner: Patricia A. Leith

Art Unit: 1654

CERTIFICATE OF MAILING (37 C.F.R. § 1.8)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: 12/28/05


Angelo J. Mignanelli

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

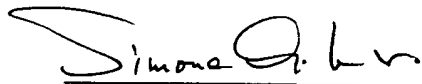
TRANSMITTAL LETTER

Enclosed herewith for filing in connection with the above-identified patent application are the following:

- 1) Request for Continued Examination (RCE);
- 2) Amendment;

- 3) Petition for a Five-Month Extension of Time; and
- 4) Acknowledgment Postcard.

Respectfully submitted,
McDermott, Will & Emery LLP

A handwritten signature in black ink, appearing to read "Simona A. Levi-Minzi", is written over a horizontal line.

Simona A. Levi-Minzi, Ph.D.
Registration No. 43,750
Attorney for Applicants

McDermott, Will & Emery LLP
201 South Biscayne Blvd.
Suite 2200
Miami, FL 33131
Telephone: 305.347.6528
Facsimile: 305.347.6500
E-Mail: SLEVI@MWE.COM

Date: December 28, 2005

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	09/919,506
Filing Date	July 31, 2001
First Named Inventor	John G. Babish
Art Unit	1654
Examiner Name	Patricia A. Leith
Attorney Docket Number	068911.0018

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

- a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
- i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ii. ☐ Other _____
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☐ Affidavit(s)/ Declaration(s)
- iii. ☐ Information Disclosure Statement (IDS)
- iv. ☐ Other _____

2. Miscellaneous


- a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
- b. ☐ Other _____

3. Fees

- The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
- The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-1133. I have enclosed a duplicate copy of this sheet.
- i. ☒ RCE fee required under 37 CFR 1.17(e)
- ii. ☒ Extension of time fee (37 CFR 1.136 and 1.17)
- iii. ☐ Other _____
- b. ☐ Check in the amount of \$ _____ enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

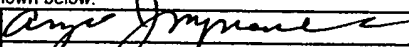
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature		Date	December 28, 2005
Name (Print/Type)	Simona A. Levi-Minzi, Ph.D.	Registration No.	43,750

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature		Date	December 28, 2005
Name (Print/Type)	Angelo J. Monanelli		

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John G. Babish, *et al.*

Serial No.: 09/919,506

Filed: July 31, 2001

Title: COMBINATIONS OF SESQUITERPENE
LACTONES AND DITERPENE LACTONES
OR TRITERPENES FOR SYNERGISTIC
INHIBITION OF CYCLOOXYGENASE-2

Attorney Docket No.: 068911.0018

Examiner: Patricia A. Leith

Art Unit: 1654

CERTIFICATE OF MAILING (37 C.F.R. § 1.8)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: 12/28/05


Angelo J. Mignanelli

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME

Applicants hereby Petition for a Five (5) Month Extension of Time, up to and including December 28, 2005. Pursuant to 1.136(a)(3), please charge Deposit Account No. 50-1133 the required fee of \$2,160.00 (37 C.F.R. § 1.17(a)(5)) .

The Commissioner is hereby authorized to charge payment of any additional fees associated with the filing submitted herewith or credit any overpayment to Deposit Account No. 50-1133.

Respectfully submitted,
McDermott, Will & Emery LLP

A handwritten signature in black ink, reading "Simona A. Levi-Minzi". The signature is fluid and cursive, with the first name "Simona" being the most prominent.

Simona A. Levi-Minzi, Ph.D.
Registration No. 43,750
Attorney for Applicants

McDermott, Will & Emery LLP
201 South Biscayne Blvd.
Suite 2200
Miami, FL 33131
Telephone: 305.347.6528
Facsimile: 305.347.6500
E-Mail: SLEVI@MWE.COM

Date: December 28, 2005

MIA 303908-1.068911.0018

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John G. Babish, *et al.*
Serial No.: 09/919,506
Filed: July 31, 2001
Title: COMBINATIONS OF SESQUITERPENE LACTONES AND DITERPENE LACTONES OR TRITERPENES FOR SYNERGISTIC INHIBITION OF CYCLOOXYGENASE-2
Attorney Docket No.: 068911.0018
Examiner: Patricia A. Leith
Art Unit: 1654

CERTIFICATE OF MAILING (37 C.F.R. § 1.8)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: 12/28/05


Angelo S. Mignanelli

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

AMENDMENT

Responsive to the Office Action mailed November 30, 2004 (the "Office Action"), entry of the following amendments, and consideration of the following remarks are respectfully requested.

Amendments to the claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 8 of this paper.

AMENDMENT TO THE CLAIMS

A listing of the claims presented in this patent application appears below. This listing replaces all prior versions and listings of the claims in this patent application.

Claims 1-15 (Cancelled).

16. (Previously amended) A composition comprising a first component comprising parthenolide and a second component selected from the group consisting of andrographolide, ursolic acid, oleanolic acid, and derivatives thereof.

17. (Original) The composition of claim 16 wherein first and second components are derived from plants or plant extracts.

18. (Original) The composition of claim 16 wherein at least one of said first or second component is conjugated with a compound selected from the group consisting of mono- or di-saccharides, amino acids, sulfates, succinate, acetate and glutathione.

19. (Original) The composition of claim 16, formulated in a pharmaceutically acceptable carrier.

20. (Currently Amended) The composition of claim 16, additionally containing one or more members selected from the group consisting of antioxidants, vitamins, minerals, proteins, fats, carbohydrates, glucosamine, chondroitin sulfate and aminosugars.

21. (Withdrawn) A method of dietary supplementation in animals comprising administering to an animal suffering symptoms of inflammation a composition of Claim 1 and continuing said administering of the composition until said symptoms are reduced.

22. (Withdrawn) The method of claim 21 wherein the composition is formulated in a dosage form such that said administration provides from 0.05 to 5.0 mg body weight per day of

each sesquiterpene lactone species, and from 0.5 to 20.0 mg/kg bodyweight per day of each diterpene lactone species or triterpene species.

23. (Withdrawn) The method of claim 21, wherein the composition is administered in an amount sufficient to maintain a serum concentration of 0.001 to 10 μ M of each sesquiterpene lactone species and from 0.001 to 10 μ M of each diterpene lactone or triterpene species.

24. (Withdrawn) The method of claim 21 wherein said animal is selected from the group consisting of humans, non-human primates, dogs, cats, birds, horses and ruminants.

25. (Withdrawn) The method of claim 21 wherein administration is by a means selected from the group consisting of oral, parenteral, topical, transdermal and transmucosal delivery.

26. (Withdrawn) The method of Claim 21, wherein the first component is selected from the group consisting of parthenolide, encelin, leucanthin B, enhydrin, melapomdin A, tenulin, confertiflorin, burrodin, psilostachyin A, costunolide, strigol, and helenalin; and the second component is selected from the group consisting of andrographolide, dehydroandrographolide, deoxyandrographolide, aneoandrographolide, ursolic acid, oleanolic acid, betulin, betulinic acid, glycyrrhetic acid, glycyrrhizic acid, triperin, and derivatives thereof.

27. (Withdrawn) The method of claim 26 wherein the composition is formulated in a dosage form such that said administration provides from 0.05 to 5.0 mg body weight per day of each sesquiterpene lactone species, and from 0.5 to 20.0 mg/kg bodyweight per day of each diterpene lactone species or triterpene species.

28. (Withdrawn) The method of claim 26, wherein the composition is administered in an amount sufficient to maintain a serum concentration of 0.001 to 10 μ M of each sesquiterpene lactone species and from 0.001 to 10 μ M of each diterpene lactone or triterpene species.

29. (Withdrawn) The method of Claim 21, wherein the first component is selected from the group consisting of parthenolide, encelin, leucanthin B, enhydrin, and melapomdin A; and the second component is selected from the group consisting of andrographolide, dehydroandrographolide, deoxyandrographolide, neoandrographolide, ursolic acid, oleanolic acid, betulin, betulinic acid, glycyrrhetic acid, glycyrrhizic acid, triperin, and derivatives thereof.

30. (Withdrawn) The method of Claim 21, wherein the first component comprises parthenolide and; the second component is selected from the group consisting of andrographolide, ursolic acid, oleanolic acid, and derivatives thereof.

31. (Withdrawn) The method of therapeutic treatment in animals comprising administering to an animal suffering symptoms of arthritis a composition of Claim 1 and continuing said administering of the composition until said symptoms are reduced.

32. (Withdrawn) The method of Claim 31, wherein the first component is selected from the group consisting of parthenolide, encelin, leucanthin B, enhydrin, melapomdin A, tenulin, confertiflorin, burrodin, psilostachyin A, costunolide, strigol, and helenalin; and the second component is selected from the group consisting of andrographolide, dehydroandrographolide, deoxyandrographolide, neoandrographolide, ursolic acid, oleanolic acid, betulin, betulinic acid, glycyrrhetic acid, glycyrrhizic acid, triperin, and derivatives thereof.

33. (Withdrawn) The method of Claim 31, wherein the first component is selected from the group consisting of parthenolide, encelin, leucanthin B, enhydrin, and melapomdin A; and the second component is selected from the group consisting of andrographolide, dehydroandrographolide, deoxyandrographolide, neoandrographolide, ursolic acid, oleanolic acid, betulin, betulinic acid, glycyrrhetic acid, glycyrrhizic acid, triperin, and derivatives thereof.

34. (Withdrawn) The method of Claim 31, wherein the first component comprises parthenolide and the second component is selected from the group consisting of andrographolide, ursolic acid, oleanolic acid, and derivatives thereof.

35. (Withdrawn) A method of therapeutic treatment comprising applying to the skin of a human suffering symptoms of acne rosacea a lotion comprising a composition of Claim 1 and continuing said administering of the composition until said symptoms are reduced.

36. (Withdrawn) The method of Claim 35, wherein the first component is selected from the group consisting of parthenolide, encelin, leucanthin B, enhydrin, melapomdin A, tenulin, confertiflorin, burrodin, psilostachyin A, costunolide, strigol, and helenalin; and the second component is selected from the group consisting of andrographolide, dehydroandrographolide, deoxyandrographolide, neoandrographolide, ursolic acid, oleanolic acid, betulin, betulinic acid, glycyrrhetic acid, glycyrrhizic acid, triperin, and derivatives thereof.

37. (Withdrawn) The method of Claim 35, wherein the first component is selected from the group consisting of parthenolide, encelin, leucanthin B, enhydrin, and melapomdin A; and the second component is selected from the group consisting of andrographolide, dehydroandrographolide, deoxyandrographolide, neoandrographolide, ursolic acid, oleanolic acid, betulin, betulinic acid, glycyrrhetic acid, glycyrrhizic acid, triperin, and derivatives thereof.

38. (Withdrawn) The method of Claim 35, wherein the first component comprises parthenolide and the second component is selected from the group consisting of andrographolide, ursolic acid, oleanolic acid, and derivatives thereof.

39. (Withdrawn) A method of therapeutic treatment comprising applying to the skin of a human suffering symptoms of psoriasis a lotion comprising a composition of Claim 1 and continuing said administering of the composition until said symptoms are reduced.

40. (Withdrawn) The method of Claim 39, wherein the first component is selected from the group consisting of parthenolide, encelin, leucanthin B, enhydrin, melapomdin A, tenulin, confertiflorin, burrodin, psilostachyin A, costunolide, strigol, and helenalin; and the second component is selected from the group consisting of andrographolide, dehydroandrographolide, deoxyandrographolide, neoandrographolide, ursolic acid, oleanolic acid, betulin, betulinic acid, glycyrrhetic acid, glycyrrhizic acid, triperin, and derivatives thereof.

41. (Withdrawn) The method of Claim 39, wherein the first component is selected from the group consisting of parthenolide, encelin, leucanthin B, enhydrin, and melapomdin A; and the second component is selected from the group consisting of andrographolide, dehydroandrographolide, deoxyandrographolide, neoandrographolide, ursolic acid, oleanolic acid, betulin, betulinic acid, glycyrrhetic acid, glycyrrhizic acid, triperin, and derivatives thereof.

42. (Withdrawn) The method of Claim 39, wherein the first component comprises parthenolide and the second component is selected from the group consisting of andrographolide, ursolic acid, oleanolic acid, and derivatives thereof.

Claims 43-57 (Cancelled).

58. (Previously amended) A composition comprising as a first component an effective amount of pharmaceutical grade parthenolide and an effective amount of a pharmaceutical grade second component selected from the group consisting of andrographolide, ursolic acid, oleanolic acid, and derivatives thereof.

59. (Previously presented) The composition of claim 58, wherein the first and second components are derived from plants or plant extracts.

60. (Previously presented) The composition of claim 58, wherein at least one of said first or second component is conjugated with a compound selected from the group consisting of mono- or di-saccharides, amino acids, sulfates, succinate, acetate and glutathione.

61. (Previously presented) The composition of claim 58, formulated in a pharmaceutically acceptable carrier.

62. (Previously presented) The composition of claim 58, additionally containing one or more members selected from the group consisting of antioxidants, vitamins, minerals, proteins, fats, carbohydrates, glucosamine, chondroitin sulfate and aminosugars.

Claims 63 and 64. (Cancelled)

REMARKS

I. CLAIMS AMENDMENTS

Claims 1-15 , 43-57, and claims 63 and 64 are cancelled. Applicants reserve the right to pursue these claims without prejudice in a separate application.

Claim 20 has been amended to rectify an apparent typographical mistake. Support for the amendment is found in the application as filed.

Applicants respectfully submit that none of these amendments introduces new matter.

II. CLAIMS 16-20 AND 58-62 SHOULD BE ALLOWED

At page 9-10 of the Office Action mailed April 07, 2004, under the header titled "ALLOWABLE SUBJECT MATTER" Examiner P. Patten stated that "[c]laims 16-20 and 58-62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims."

In the Amendment filed on September 02, 2004, Applicants amended claims 16 and 58 to independent form as per the Examiner's comments (see *supra*).

In the subsequent Office Action mailed November 30, 2004, Examiner P. Patten (now married as P. Leith) reiterated the objection to claims 16-20 and 58-62. A review of the record on PAIR confirmed that our amendment was entered on the record.


In a conference call held on March 02, 2005 with Examiner B. Campell (the Supervisory Examiner in the case) confirmed that the allowable claims in the amended form should be allowed and suggested resubmitting the same to rectify the apparent oversight.

Accordingly, Applicants respectfully request the earnest allowance of allowable claims 16-20 and 58-62 as previously amended to independent form.

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request reconsideration of the claims and a notice to this effect. The Examiner is invited to call the undersigned to expedite prosecution.

A Request for a Five (5) Month Extension of Time, up to and including December 28, 2005 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under paragraph 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,
McDERMOTT, WILL & EMERY LLP


Simona A. Levi-Minzi, Ph.D.
Registration No. 43,750
Attorney for Applicants

McDermott, Will & Emery LLP
201 South Biscayne Blvd.
Suite 2200
Miami, FL 33131
Telephone: 305.347.6528
Facsimile: 305.347.6500
E-Mail: SLEVI@MWE.COM

Date: December 28, 2005